# EPA Registration File 2596-182

# DATA EXTRACTION REQUEST

Reg # 259(07) Decision #
Description:
Material Sent:
Electronic Label/Letter Dated 10123py dest all (See PPLS for electronic file)
Stamped Label Dated (See jacket)
☐ Notification Dated (See jacket)
☐ New CSF(s) Dated (See jacket)
☐ Other:
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.
Reviewer: Autumn Metzger
Division: RD - IRB
Phone: 305-5314
Date: \\\\2014



#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

2596-182

Date of Issuance:

EPA Reg. Number:

10/23/2012 4

J	0	П	CE	OF	PI	FST	П	CI	D	F.
ч				111		11.7			1	2.

X Registration Reregistration (under FIFRA, as amended) Term of Issuance:

Conditional

Name of Pesticide Product:

Hartz Reference #147

Name and Address of Registrant (include ZIP Code):

The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. This registration is time-limited and expires two years from the date this product is first released for shipment.

You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.

continue next page		
Signature of Approving Official:	Date:	
Venus Eagle	10/23/2014	
Venus Eagle, Product Manager 01		
Invertebrate-Vertebrate Branch 3 Registration Division (7505P)		

EPA Form 8570-6

- Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2015.

Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)

Age: months or years Sex: M, F, or neutered Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

- 4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - a. All incidents should be reported including all minor dermal and ocular irritation reports.
  - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
  - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
  - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
  - e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
  - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
  - g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
  - h. Table showing number of incidents for each dog breed.
  - i. Table showing number of incidents in dogs for each clinical sign.
  - j. Table showing number of incidents in dogs for each organ system.
- 5. Report aggregate incidents, but do not combine moderate and minor incidents.
- Submit and/or cite all data required for registration/registration/registration review of your
  product under FIFRA when the Agency requires all registrants of similar products to submit such
  data.

Page 4 of 4 EPA Reg. No. 2596-182 Decision No. 486441

- 7. You are required to comply with the DCIs identified below:
  - a. Imidacloprid GDCI-129099-951, issued on 11/10/2010
  - b. Pyriproxyfen GDCI- 129032-1299, issued on 2/21/2014

If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts\_prd.htm

- 8. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 9. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 2596-182."
- 10. Submit one copy of the final printed label for the record before you release the product for shipment.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

Basic CSF dated 8/28/2014

If you have any questions, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Venus Eagle, Product Manager 01 Invertebrate-Vertebrate Branch 3 Registration Division (7505P)

Attachment -stamped label

# [FRONT PANEL] Hartz® Reference # 147

Alternate Brand Names

Hartz First Defense Max for Dogs [& or and Puppies]

Hartz First Defense Advanced PLUS for Dogs [& or and Puppies]

Hartz First Defense Advanced PRO for Dogs [& or and Puppies]

Hartz First Defense Evolution for Dogs [& or and Puppies]

Hartz First Defense Guardian for Dogs [& or and Puppies]

Hartz Generic Flea Topical Treatment for Dogs [& or and Puppies]

Hartz Generic Flea Topical for Dogs [& or and Puppies]

Hartz First Defense ADVANCED for Dogs [& or and Puppies]

Hartz ADVANCED for Dogs [& or and Puppies]

Hartz ADVANCE PRO for Dogs [& or and Puppies]

Hartz UltraGuard Sentinel MAX for Dogs [& or and Puppies]

Hartz UltraGuard Sentinel PLUS for Dogs [& or and Puppies]

Hartz UltraGuard Sentinel PRO for Dogs [& or and Puppies]

Hartz UltraGuard Defender for Dogs [& or and Puppies]

Hartz UltraShield for Dogs [& or and Puppies]

Hartz ImidaShield MAX for Dogs [& or and Puppies]

Hartz ImidaShield PLUS for Dogs [& or and Puppies]

Hartz ImidaShield PRO for Dogs [& or and Puppies]

Hartz ImidaShield II MAX for Dogs [& or and Puppies]

Hartz ImidaShield II PLUS for Dogs [& or and Puppies]

Hartz ImidaShield II PRO for Dogs [& or and Puppies]

Hartz ImidaGuard MAX for Dogs [& or and Puppies]

Hartz ImidaGuard PLUS for Dogs [& or and Puppies]

Hartz ImidaGuard PRO for Dogs [& or and Puppies]

Hartz ImidaGuard II MAX for Dogs [& or and Puppies]

Hartz ImidaGuard II PLUS for Dogs [& or and Puppies]

Hartz ImidaGuard II PRO for Dogs [& or and Puppies]

Hartz ProCare for Dogs [& or and Puppies]

Hartz FirstCare for Dogs [& or and Puppies]

[Each of the above brands will be packaged in the weight classes designated below:]

For use ONLY on Dogs [and Puppies] 7 weeks and older weighing 3 - 10 lbs.

or weighing 11 - 20 lbs.

or weighing 21 - 55 lbs.

or weighing over 55 lbs.

# [FRONT PANEL (cont.)]

#### **ACTIVE INGREDIENTS:**

Imidacloprid	9.10%
Pyriproxyfen	
Other Ingredients.	90.44%
Total	100.00%

# ACCEPTED

10/23/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg No. 2596-182

#### KEEP OUT OF REACH OF CHILDREN

**CAUTION:** See back panel for precautionary statements and directions for use. [Large clear picture of dog in appropriate breed/weight class on front panel of product to be included]

#### **NET CONTENTS:**

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	Contains 1 tube, each 0.013 fl. oz. (0.40 ml.)
11 to 20 lbs.	Contains 1 tube, each 0.034 fl. oz. (1.00 ml.)
21 to 55 lbs.	Contains 1 tube, each 0.084 fl. oz. (2.50 ml.)
55 lbs. and Over	Contains 1 tube, each 0.135 fl. oz. (4.00 ml.)

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	0.039 fl. oz. (1.20 ml.),
	Contains 3 tubes, each 0.013 fl. oz. (0.40 ml.)
11 to 20 lbs.	0.102 fl. oz. (3.00 ml.),
	Contains 3 tubes, each 0.034 fl. oz. (1.00 ml.)
21 to 55 lbs.	0.252 fl. oz. (7.5 ml.),
	Contains 3 tubes, each 0.084 fl. oz. (2.50 ml.)
55 lbs. and Over	0.405 fl. oz. (12.00 ml.),
	Contains 3 tubes, each 0.135 fl. oz. (4.00 ml.)

# [FRONT PANEL (cont.)]

#### NET CONTENTS (cont.):

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)		
3 to 10 lbs.	0.052 fl. oz. (1.60 ml.),		
	Contains 4 tubes, each 0.013 fl. oz. (0.40 ml.)		
11 to 20 lbs.	0.136 fl. oz. (4.00 ml.),		
	Contains 4 tubes, each 0.034 fl. oz. (1.00 ml.)		
21 to 55 lbs.	0.336 fl. oz. (10.00 ml.),		
	Contains 4 tubes, each 0.084 fl. oz. (2.50 ml.)		
55 lbs. and Over	0.540 fl. oz. (16.00 ml.),		
	Contains 4 tubes, each 0.135 fl. oz. (4.00 ml.)		

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:			
3 to 10 lbs.	0.078 fl. oz. (2.40 ml.),		
	Contains 6 tubes, each 0.013 fl. oz. (0.40 ml.)		
11 to 20 lbs.	0.204 fl. oz. (4.00 ml.),		
	Contains 6 tubes, each 0.034 fl. oz. (1.00 ml.)		
21 to 55 lbs.	0.504 fl. oz. (15.00 ml.),		
	Contains 6 tubes, each 0.084 fl. oz. (2.50 ml.)		
55 lbs. and Over	0.810 fl. oz. (24.00 ml.),		
	Contains 6 tubes, each 0.135 fl. oz. (4.00 ml.)		



DO NOT USE ON CATS [1.5 x 1.5 cm black on yellow background]

## [BACK PANEL]

#### PRECAUTIONARY STATEMENTS

#### **HAZARDS TO HUMANS**

**CAUTION**: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

#### HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age or weighing less than [3lbs.; 11lbs.; 21lbs.; 55lbs.] As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a Veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

#### PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not store hear heat or open flame.

#### **FIRST AID**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies or consumer questions call 1-800-275-1414.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment or advice.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

#### READ ENTIRE LABEL BEFORE EACH USE

#### RESTRICTIONS

USE ONLY ON DOGS OR ON PUPPIES 7 WEEKS OF AGE OR OLDER WEIGHING [3 to 10 lbs.; 11 to 20 lbs.; 21 to 55 lbs.; Over 55 lbs.]

DO NOT USE ON OTHER ANIMALS

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR DOGS

DO NOT APPLY MORE THAN ONE (1) TUBE PER TREATMENT

DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH

TREATED AREA UNTIL COMPLETELY DRY

**Side Effects:** Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call 1-800-275-1414.



[1.5 x 1.5 cm black on yellow background]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

# [DIRECTIONS FOR USE (CONT.)]

[APPLICATION INSTRUCTIONS:]

[Visuals Depicting How to Open Applicator Tube and Application to Animal]

[OPTION 1: for 3 to 10 lbs. or 11 to 20 lbs. packages]

#### HOW TO APPLY

- 1. Remove one applicator tube from the package.
- 2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.
- 3. Turn the cap around and place other end of cap back on tube.
- 4. Twist cap to break seal, then remove cap from tube.
- 5. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your dog's eyes or allow your dog to ingest this product. Do not allow the product to run off.
- 6. Discard empty tube as described in the Storage and Disposal section.
- 7. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[OPTION 2: for 3 to 10 lbs. or 11 to 20 lbs. packages]

#### HOW TO APPLY

- 1. Remove one applicator tube from the package.
- 2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
- 3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
- 4. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your dog's eyes or allow your dog to ingest this product*. Do not allow the product to run off.
- 5. Discard empty tube as described in the Storage and Disposal section.
- 6. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

#### [DIRECTIONS FOR USE (CONT.)]

[APPLICATION INSTRUCTIONS (cont.):]

[OPTION 3: for 21 to 55 lbs. and Over 55 lbs. packages]

#### HOW TO APPLY

- 1. Remove one applicator tube from the package.
- 2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.
- 3. Turn the cap around and place other end of cap back on tube.
- 4. Twist cap to break seal, then remove cap from tube.
- 5. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. Do not get this product in your dog's eyes or allow your dog to ingest this product.
- 6. Discard empty tube as described in the Storage and Disposal section.
- 7. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

# [OPTION 4: for 21 to 55 lbs. and Over 55 lbs. packages] **HOW TO APPLY**

- 1. Remove one applicator tube from the package.
- 2. Hold applicator tube in an upright position facing away from you and your pet's face and eves.
- 3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
- 4. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. Do not get this product in your dog's eyes or allow your dog to ingest this product.
- 5. Discard empty tube as described in the Storage and Disposal section.
- 6. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Store in a cool, dry place inaccessible to children and pets.

#### PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-275-1414 for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation. Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Oct. 22, 2014

#### [INSTRUCTIONS FOR BLISTER PACK]

#### HOW TO OPEN



#### [OPTION 1:]

- 1. Being careful not to cut close to the blister cavities, take scissors and cut along dotted line.
- 2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
- 3. Follow application instructions.
- 4. Repeat steps 1 and 2 for each tube.

#### [OPTION 2:]

- 1. Separate [foil] [paper] from corner of blister package.
- 2. Peel back [foil] [paper] and take out the tube.

#### INDIVIDUAL TUBE TEXT

Insert Product name

[The appropriate size and fill volume will be correctly used on each applicable dog's weight category]

Only for Use on Dogs and Puppies 7 Weeks or Older Weighing [insert text with weight and fill volume from a line immediately below]

3 to 10 lbs. - 0.014 fl. oz. (0.4 ml.)

11 to 20 lbs. - 0.034 fl. oz. (1.0 ml.)

21 to 55 lbs. - 0.084 fl. oz. (2.5 ml.)

Over 55 lbs. - 0.135 fl. oz. (4.0 ml.)

9.10% Imidacloprid

0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read the Entire Label before Use

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

(Lot No. is heat stamped in tube crimp- required number)

MASTER LABEL-

#### OPTIONAL/ALTERNATE LABEL TEXT

For use on dogs and puppies 7 weeks of age and older

(Product Name) contains Imidacloprid and (an/the) insect growth regulator or IGR or

Pyriproxyfen

A single topical application remains effective for [4 weeks] [1 month]

Convenient, easy-to-apply topical solution

Convenient, easy-to-apply [and fragrance free] [monthly] [topical solution]

Once a month topical flea treatment for dogs 7 weeks of age or older

(Product Name) is indicated for the prevention and treatment of fleas on dogs 7 weeks of age and older

For the treatment and prevention of flea [and lice] infestations

One treatment prevents further flea infestations for [4 weeks] [1 month] [30 days]

Kills larval stages of fleas

Stops existing flea infestations by killing adult fleas

[Prevents] [Stops] flea eggs from hatching [or developing] [into biting adults]

Effectively breaks the flea life cycle

Effectively targets all [life] stages of [fleas]

[Kills] [Controls] all flea life stages

3-way flea protection ([kills] [controls] adults, larvae, and eggs)

[Prevents] [Stops] flea eggs [and flea larvae] from developing into [(biting)

(adult)] fleas

Treatment with (Product Name) kills fleas which may cause flea allergic dermatitis [FAD] [or flea bite hypersensitivity]

Flea adulticide, larvicide, and ovicide

Kills flea eggs

Controls highly [irritating] [annoying] [flea] [insect] bites

Controls flea problems (on dogs or on dogs and puppies)

Provides flea protection (on dogs *or* on dogs and puppies)

Controls existing fleas and flea eggs [(plus) (and)] [prevents] future flea infestations in the home Starts working through contact

Use flea [prevention] [protection] year-round

Contains an insect growth regulator (IGR) to kill flea eggs and prevent reinfestation

Monthly use of (Product Name) kills fleas which may cause ([flea allergy dermatitis] [flea bite hypersensitivity])

Multi-stage flea control

Prevents fleas on treated dogs from infesting (reinfesting) your home

Kills fleas which may serve as intermediate hosts for tapeworms

Kills [(biting) (chewing)] lice

For treatment and prevention of [(biting) (chewing)] lice [infestations] [on dogs or on dogs and puppies]

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

Stops existing [(biting) (chewing)] lice infestations

Dual protection against fleas and lice

Treats, prevents and controls [(biting) (chewing)] lice [infestations]

Provides effective control of [(biting) (chewing)] lice [infestations]

Kills [(biting) (chewing)] lice and prevents further infestations

For treatment and prevention of infestations with [(biting) (chewing)] lice
Remains effective after bathing and/or swimming
Remains effective following swimming and/or shampooing
Waterproof
Remains effective after exposure to rain

Prevents (establishment of) new infestations after application

Prevents all flea stages (eggs, larvae) from developing Prevents all flea stages (eggs, larvae, pupae) from developing Kills fleas, flea eggs, larvae, pupae [for] [4 weeks] [1 month] [30 days]

Stays on and doesn't rub off for 1 month (or 4 weeks)
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation (reinfestation)
Prevents and controls re-infestation (reinfestations)
Eliminates fleas
Long lasting – 4 weeks or 1 month
Effective and convenient topical treatment
(With) patented applicator
Effective after bathing
Effective after exposure to water
Easy spot on topical applicator

Remains effective even after bathing and water immersion (Product Name) remains effective even after bathing and water immersion

Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (or Advantage® II)

Contains the (same) active ingredients used in Bayer Advantage® II (or Advantage® II) (products)

Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (or Advantage® II) (brand products)

[Product Name] is not manufactured by or distributed by Bayer. Advantage® II is a registered trademark of Bayer Healthcare LLC.

Only for dogs and puppies 7 weeks of age or older Specially formulated for dogs and puppies 7 weeks of age or older

Kills fleas within [12] hours of application Kills fleas on dogs within [12] hours and continues to prevent infestations for [four weeks] [1 month] [30 days]

From:

DJones@hartz.com

Sent:

Friday, October 10, 2014 2:57 PM

To:

Metzger, Autumn

Subject:

RE: EPA File Symbols 2596-RIN and -RIE electronic Oct 10b

Attachments:

Hartz Reference #145 Master Label 2014 Oct 10b.pdf; Hartz Reference #147 Master Label

2014 Oct 10b.pdf

Autumn,

The labels with modifications are attached below. The responses are:

Blister pack - The label was copied from a Bayer master label for an imidacloprid product. Some of our drops may be packed in them. Please note these are not CRP packs and when blisters are used the complete regulatory label text is on the outside pack. Other product versions are applicator tubes in plastic bubble covers with a heavy cardboard backing. There too the full text is on the cardboard clearly visible.

Long lasting - I added "- 4 weeks or 1 month"

Deleted "in the dog's environment"

Thanks again, Dave

From: To:

"Metzger, Autumn" <Metzger, Autumn@epa.gov> "DJones@hartz.com" <DJones@hartz.com>,

10/10/2014 01:35 PM Date:

RE: EPA File Symbols 2596-RIN and -RIE Subject:

My only question is you still have optional directions for a blister pack but I thought you said there wasn't a blister pack included.

Also, need to qualify "long lasting" claim (with 4 weeks/1 month)

And I missed the claim "Kills larval stages of fleas in the dog's environment"...need to delete the part of "in the dog's environment"

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]

Sent: Friday, October 10, 2014 10:53 AM

To: Metzger, Autumn

Cc: SMcNear@hartz.com

Subject: EPA File Symbols 2596-RIN and -RIE

#### Good morning,

I have attached the labels modified per edits. There are two lines I retained with the within 12 hour claim. I have attached the DER for the MRIDs supporting those claims in addition to the two labels and a copy of the e-mail indicating recent agency acceptance of them. Those 12 hour claims are both at the bottom of page 11 of 12 of the attached labels. I believe I incorporated all the other edits.

The two other cat labels will be following shortly.

Thank you again for all the time and effort you put into these applications.

Sincerely,

Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

yes proper ator

From:

DJones@hartz.com

Sent:

Friday, October 10, 2014 11:40 AM

To: Cc:

Metzger, Autumn SMcNear@hartz.com

Subject:

RE: EPA File Symbols 2596-RIN and -RIE

Attachments:

Hartz Reference #145 Master Label 2014 Oct 10a.pdf; Hartz Reference #147 Master Label

2014 Oct 10a.pdf

Autumn,

asod oxe of sight and sight sight of the sig Attached are modified labels with an "a" designation for version 2 with those two lines removed.

Regards.

Dave

From: To-

"Metzger, Autumn" < Metzger. Autumn@epa.gov> "DJones@hartz.com" < DJones@hartz.com>,

Date:

10/10/2014 11:29 AM

Subject:

RE: EPA File Symbols 2596-RIN and -RIE

You do not have the proper cited MRIDs for the 12 hour claim.

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]

Sent: Friday, October 10, 2014 10:53 AM

To: Metzger, Autumn Cc: SMcNear@hartz.com

Subject: EPA File Symbols 2596-RIN and -RIE

Good morning,

I have attached the labels modified per edits. There are two lines I retained with the within 12 hour claim. I have attached the DER for the MRIDs supporting those claims in addition to the two labels and a copy of the e-mail indicating recent agency acceptance of them. Those 12 hour claims are both at the bottom of page 11 of 12 of the attached labels. I believe I incorporated all the other edits.

The two other cat labels will be following shortly.

Thank you again for all the time and effort you put into these applications.

Sincerely.

Dave

David Jones Manager Regulatory Affairs The Hartz Mountain Corporation

1

From:

Metzger, Autumn

Sent:

Thursday, October 09, 2014 3:14 PM

To:

'DJones@hartz.com'

Subject: Attachments: 2596-RIE DOG spot on RE: Hartz Reference #147 Master Label 2014 Oct 4.doc 2596-RIE hartz spot on label imidacloprid + pyriproxyfen WITH AGENCY COMMENTS

10-9-2014.pdf

Last comments, if you can have this also back by lunch tomorrow we'll be good. Thanks!

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]

Sent: Wednesday, October 08, 2014 12:04 PM

To: Metzger, Autumn

Subject: Hartz Reference #147 Master Label 2014 Oct 4.doc

Hi,

I believe this is where it was to go. Please take a look and I will call very soon. I looked at the cat and just have a question about which claims to retain, in particular shampoo/water resistance.

Thanks Dave

From:

Metzger, Autumn

Sent:

Tuesday, October 07, 2014 2:58 PM

To:

'DJones@hartz.com'

Subject:

RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft

master labels

And just verified you are right about being able to make the comparison claim to Bayer's Advantage II since they are both the same combos.

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]

Sent: Tuesday, October 07, 2014 2:52 PM

To: Metzger, Autumn Cc: SMcNear@hartz.com

Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

#### Good afternoon,

Thank you for the response. I have been working on the 2596-RIE today. If it is ok with you I will send it to you for review. If found acceptable I can promptly modify it to the 2596-RIN by changing the product name, the EPA file number and delete the "combustible" related section.

Sincerely, Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414

From: "Metzger, Autumn" < Metzger.Autumn@epa.gov > To: "DJones@hartz.com" < DJones@hartz.com >,

Cc: "SMcNear@hartz.com" <SMcNear@hartz.com>
Date: 10/07/2014 02:21 PM

FAX: 201-271-0357

Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

#### Dear Mr. Jones,

Thank you for providing found reviews and other attached information. I've included my comments to your rebuttals below in blue:

MRID44256902 - The DER for this and the prior sequenced MRID44256901 (DER attached) shows they were

From:

Metzger, Autumn

Sent:

Wednesday, October 01, 2014 11:07 AM

To:

'DJones@hartz.com'

Subject:

2596-RIE and RIN (Hartz spot on for DOGS) Label comments

Attachments:

2596-RIE hartz spot on label imidacloprid + pyriproxyfen WITH AGENCY COMMENTS

10-1-2014.pdf

Hi Dave,

Please see attached the label comments for 2596-RIE (Dog product). We can use this for –RIN as well with the exception that RIN doesn't require the combustible language.

Let's set up a time today before 2:30 EST to go over. I'd allot 45 min.

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314 Please understand our confusion is based on no indication of a change of EPA OPP Policy in regard to the validity of the science for these referenced studies. We have not been able to find documentation showing the DERs were invalidated nor the test protocols have been updated. Without indication to the contrary Hartz contends these studies represent good science. We respectfully ask these all be considered to support the claims proposed for these subject labels.

I am working on modifying the label per comments. The it will be back to you early next week for review. Thank you again for your time and consideration in these applications.

Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Metzger, Autumn" < Metzger, Autumn@epa.gov>
To: "DJones@hartz.com" < DJones@hartz.com>,
Cc: "SMcNear@hartz.com" < SMcNear@hartz.com>

Date: 07/31/2014 01:33 PM

Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

Please find attached the efficacy reviews for 2596-RIN and 2596-RIE.

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314 acceptable to EPA. The conclusion of the attached DER states imidacloprid is effective against cat fleas, their eggs and larvae.

The attached DER was reviewing a citation of a study from 1997 in 2007, therefore the re-review is 7 years old. As stated before, the Agency does have to draw a line in the sand at some point and decide to not continue to allow citations of studies that would not be to today's standards. With that said, after discussions with other efficacy reviewers and the PM, we feel that although this study isn't up to today's standards, it is borderline enough that we'll allow the citation of it at this time.

Therefore, 44256902 can be cited to support claims against flea eggs, larvae and pupae on dogs for up to 1 month

2. MRID44256903 - The DER appears in an NPIRS search (copy attached) and is referenced in an agency Product Performance/Efficacy Review dated 2 Oct 2007 (attached). We contend it is a valid number. This data supports the shampoo resistance claim.

I am not sure why this MRID was not coming up in our system, however (based on your citation of a review) I did find the original data in Documentum and was able to review the actual data. This MRID is acceptable.

Therefore, MRID 44256903 can be cited to support claims for water immersion and shampooing (against fleas) on dogs for up to 1 month

3. MRIDs 45425101 & 45425102 - These were previously submitted in support of the other imidacloprid topical products. We ask the same consideration.

These MRIDS are of data not to any real standards of today. I do not believe they support any current claims on any products. The studies are exploratory in nature using 3 dogs (cats for -02) and attach 6 fleas to a shaved area to "examine the behavior" of the fleas.

Therefore, MRIDS 45425101 & 45425102 still do not support any claims.

Please revise your label accordingly and save this email as a record of what has been accepted.

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]

Sent: Friday, October 03, 2014 4:03 PM

To: Metzger, Autumn
Cc: SMcNear@hartz.com

Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

#### Good afternoon,

First thank you for sending the label with the edits and taking the time to discuss them with my on October 1. Upon reviewing the label comments with our marketing and management teams, there are concerns about the deleted claims. In response to the attached memo, we offer the following comments and observations:

- 1. MRID44256902 The DER for this and the prior sequenced MRID44256901 (DER attached) shows they were acceptable to EPA. The conclusion of the attached DER states imidacloprid is effective against cat fleas, their eggs and larvae
- 2. MRID44256903 The DER appears in an NPIRS search (copy attached) and is referenced in an agency Product Performance/Efficacy Review dated 2 Oct 2007 (attached). We contend it is a valid number. This data supports the shampoo resistance claim.
- 3. MRIDs45425101 & 45425102 These were previously submitted in support of the other imidacloprid topical products. We ask the same consideration.



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

# OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)



BARCODE No.: 419022; DECISION No.: 486441 FILE SYMBOL No.: 2596-RIE;

PRODUCT NAME: Hatrz Reference #147; PC Code(s): 129099&129032; Action Code: R315;

DATE:

September 2, 2014

SUBJECT:

Product Chemistry Review of Hartz Reference #147

FROM:

Akiva Abramovitch, Ph.D.

Technical Review Branch / RD (7505P)

Spor 9110714

THROUGH: Shyam Mathur, Ph.D.

Product Chemistry Team Leader Technical Review Branch/RD (7505P)

TO:

Autumn Metzger/Venus Eagle, PM 1

Insecticide-Rodenticide Branch/RD (7505C)

#### INTRODUCTION:

The applicant has submitted an application for registration of a new end use product containing Imidacloprid at 9.1% and Pyriproxyfen (Nylar) at 0.46%. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 492878-01 through 492878-03).

The CSF of the basic formulation dated August 28, 2014 (Replaces the December 1, 2013 CSF) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSF dated 8/28/14.

#### SUMMARY OF FINDINGS:

- 1. Name of Active Ingredient: Imidacloprid (9.1%) and Nylar/Pyriproxyfen (0.46%).
- 2. Has the registrant claimed substantial similarity to a registered product?
  - [ ] Yes; [X] No; [ ] NA; if yes give the registration number of the cited product.
- All the source materials for the active ingredients are derived from the registered sources: [X] Yes; [] No.
- All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: [X] Yes; [] No.

	ARCODE No.: 419022; DECISION No.: 486441 FILE SYMBOL No.: 2596-RIE; RODUCT NAME: Hatrz Reference #147; PC Code(s): 129099&129032; Action Code: R315;
5.	Confidential Statement of Formula(s):
	[X] Basic CSF dated August 28, 2014 (Replaces the December 1, 2013 CSF) Alternate CSFs- None
6.	Product label
	<ul> <li>a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product labe (PR Notice 91-2).</li> </ul>
	[] Yes, if not, explain below: Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient) [] Yes; [] No; if not, explain below:
	Metallic equivalent: [ ] Yes [X] NA; Soluble arsenic: [ ] Yes [X] NA Isomeric ratios: [ ] Yes [X] NA Acid equivalent: [ ] Yes [X] NA; {name} acid equivalent = xx %
	b. Health related sub statements: Product contains?
	Petroleum distillate at > 10%: [ ] Yes [X] No [ ] NA  Methanol at > 4%: [ ] Yes [X] No [ ] NA  Sodium nitrate/Sodium nitrite [ ] Yes [X] No [ ] NA
	<ul> <li>c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?</li> <li>[X] Yes [] No</li> </ul>
	Flash point 142 F. Add to the label under the Precautionary Statements in compliance with 156.78
	"Combustible. Do not use or store near heat or open flame"
	Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)? [] Yes, [] No, [X] NA, if not, explain below:

d. Label requires an additional Storage and Disposal statement:

[] Yes [X] No

BARCODE No.: 419022; DECISION No.: 486441 FILE SYMBOL No.: 2596-RIE; PRODUCT NAME: Hatrz Reference #147; PC Code(s): 129099&129032; Action Code: R315;

#### 7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline	Study Title		Data submitted		TRB's Assessment	MRID Nos.
No.			Yes No		of Data	
830.1550	Product Identity & Composition		X		Α	492878-02
830.1600	Description of materials used to produce the product		X		A	492878-02
830.1650	Description of formulation process		X		A	492878-02
830.1670	Discussion on the formation of impurities		X		A	492878-02
830.1700	Preliminary analysis				NA	
- 3	Certified Limits (158.350) Proposed Limits  Justification for wider limits		X		A	
830.1750						492878-02
830.1800	Enforcement analytical method		X		A	492878-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

BARCODE No.: 419022; DECISION No.: 486441 FILE SYMBOL No.: 2596-RIE; PRODUCT NAME: Hatrz Reference #147; PC Code(s): 129099&129032; Action Code: R315;

#### 8. Group B:

Guideline Study Title No.		Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Light yellow clear liquid with a solvent like odor	A	492879-01
830.6314	Oxidation/ Reduction	Components are not expected to React with oxidizing and reducing agents	w	492878-09 and 492878-01
830.6315	Flammability	142.5 F	A	492878-01
830.6316	Explodability	Not explosive	A	492878-01
830.6317	Storage Stability	A study in progress	G	
830.6320	Corrosion	A study in progress	G	
830.7000	рН	7.4	А	492878-01
830.7300	Density (units)	9.789 lb/gal	A	492878-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I= In progress, U = Upgradeable.

BARCODE No.: 419022; DECISION No.: 486441 FILE SYMBOL No.: 2596-RIE; PRODUCT NAME: Hatrz Reference #147; PC Code(s): 129099&129032; Action Code: R315;

#### CONCLUSION:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

- 1. The proposed CSF for the basic formulation dated August 28, 2014 is acceptable.
- 2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
- 3. The registrant satisfied the Group B data requirements with the exception of the Storage Stability and Corrosion data requirements. The pH was provided as requested by the Agency and reported at 7.4 on the revised CSF.
- 4. Add to the label under the Precautionary Statements in compliance with 156.78

"Combustible. Do not use or store near heat or open flame"

From:

Metzger, Autumn

Sent:

Tuesday, October 07, 2014 2:19 PM

To: Cc: 'DJones@hartz.com' SMcNear@hartz.com

Subject:

RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft

master labels

Dear Mr. Jones,

Thank you for providing found reviews and other attached information. I've included my comments to your rebuttals below in blue:

 MRID44256902 - The DER for this and the prior sequenced MRID44256901 (DER attached) shows they were acceptable to EPA. The conclusion of the attached DER states imidacloprid is effective against cat fleas, their eggs and larvae.

The attached DER was reviewing a citation of a study from 1997 in 2007, therefore the re-review is 7 years old. As stated before, the Agency does have to draw a line in the sand at some point and decide to not continue to allow citations of studies that would not be to today's standards. With that said, after discussions with other efficacy reviewers and the PM, we feel that although this study isn't up to today's standards, it is borderline enough that we'll allow the citation of it at this time.

Therefore, 44256902 can be cited to support claims against flea eggs, larvae and pupae on dogs for up to 1 month

2. MRID44256903 - The DER appears in an NPIRS search (copy attached) and is referenced in an agency Product Performance/Efficacy Review dated 2 Oct 2007 (attached). We contend it is a valid number. This data supports the shampoo resistance claim.

I am not sure why this MRID was not coming up in our system, however (based on your citation of a review) I did find the original data in Documentum and was able to review the actual data. This MRID is acceptable.

Therefore, MRID 44256903 can be cited to support claims for water immersion and shampooing (against fleas) on dogs for up to 1 month

3. MRIDs 45425101 & 45425102 - These were previously submitted in support of the other imidacloprid topical products. We ask the same consideration.

These MRIDS are of data not to any real standards of today. I do not believe they support any current claims on any products. The studies are exploratory in nature using 3 dogs (cats for -02) and attach 6 fleas to a shaved area to "examine the behavior" of the fleas.

Therefore, MRIDS 45425101 & 45425102 still do not support any claims.

Please revise your label accordingly and save this email as a record of what has been accepted.

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314 From: DJones@hartz.com [mailto:DJones@hartz.com]

Sent: Friday, October 03, 2014 4:03 PM

To: Metzger, Autumn Cc: SMcNear@hartz.com

Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

#### Good afternoon,

First thank you for sending the label with the edits and taking the time to discuss them with my on October 1. Upon reviewing the label comments with our marketing and management teams, there are concerns about the deleted claims. In response to the attached memo, we offer the following comments and observations:

- MRID44256902 The DER for this and the prior sequenced MRID44256901 (DER attached) shows they were acceptable to EPA. The conclusion of the attached DER states imidacloprid is effective against cat fleas, their eggs and larvae.
- 2. MRID44256903 The DER appears in an NPIRS search (copy attached) and is referenced in an agency Product Performance/Efficacy Review dated 2 Oct 2007 (attached). We contend it is a valid number. This data supports the shampoo resistance claim.
- 3. MRIDs45425101 & 45425102 These were previously submitted in support of the other imidacloprid topical products. We ask the same consideration.

Please understand our confusion is based on no indication of a change of EPA OPP Policy in regard to the validity of the science for these referenced studies. We have not been able to find documentation showing the DERs were invalidated nor the test protocols have been updated. Without indication to the contrary Hartz contends these studies represent good science. We respectfully ask these all be considered to support the claims proposed for these subject labels.

I am working on modifying the label per comments. The it will be back to you early next week for review. Thank you again for your time and consideration in these applications.

Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414

FAX: 201-271-0357

From: "Metzger, Autumn" < Metzger, Autumn@epa.gov > To: "DJones@hartz.com" < DJones@hartz.com" >, Cc: "SMcNear@hartz.com" < SMcNear@hartz.com > 07/31/2014 01:33 PM

Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

#### **MEMORANDUM:**

To: Autumn Metzger

From: Autumn Metzger, M.S.

Date: 10/23/2014

Subject: PRODUCT PERFORMANCE REVIEW ADDENDUM

EPA Reg No/EPA File Symbols: 2596-RIN, Decision #486509,

EPA Reg No/EPA File Symbols: 2596-RIN, Decision #486509, DP Barcode: 419034 EPA Reg No/EPA File Symbols: 2596-RIE, Decision #486441, DP Barcode: 419024

PRIA action code: R315

Formulation Type: Spot-ons

Ingredients statement from the label with PC codes included:

Imidacloprid, 129099 (9.1%) Pyriproxyfen 129032 (0.44%)

Application rate(s) of product and each active ingredient:

Imidacloprid- 10 lb dog = 9.42 mg/kg 20 lb dog = 11.79 mg/kg 55 lb dog = 10.71 mg/kg

Pyriproxyfen- 10 lb dog = 0.48 mg/kg 20 lb dog = 0.60 mg/kg 55 lb dog = 0.54 mg/kg

Background: ADDENDUM TO EFFICACY REIVEW DP 419034 & 419024 (A. METZGER, 7/24/2014) TO UP DATE ALLOWABLE CLAIMS

The following MRIDs are found to be acceptable for citation for the following claims:

MRID 44259601 - added to data matrix to support claim: "kills fleas within 12 hours of application on dogs."

MRID 44256902 – we will allow citation of this MRID to support claims against flea eggs, larvae and pupae on dogs for up to 1 month

MRID 44256903 – originally the MRID was not found in system so I marked it as invalid (as it was found in OPPIN), but found I found the study in documentum and company provided original review. Therefore, this MRID can be used to support water immersion and shampooing claims against fleas on dogs for up to 1 month.



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

#### MEMORANDUM:

Date: 7/24/14

To: Venus Eagle, PM 1

From: Autumn Metzger, M.S.

Subject: PRODUCT PERFORMANCE REVIEW - citations of efficacy data

EPA Reg No/EPA File Symbols: 2596-RIN,

Decision #486509,

DP Barcode: 419034

EPA Reg No/EPA File Symbols: 2596-RIE,

Decision #486441. DP Barcode: 419024

PRIA action code: R315

Formulation Type: Spot-on for dogs

Ingredients statement from the label with PC codes included:

Imidacloprid, 129099 (9.1%) Pyriproxyfen, 129032 (0.44%)

Application rate(s) of product and each active ingredient:

Imidacloprid: 10 lb dog = 9.42 mg/kgPyriproxyfen: 10 lb dog = 0.48 mg/kg 20 lb dog = 11.79 mg/kg20 lb dog = 0.60 mg/kg

55 lb dog = 10.71 mg/kg

55 lb dog = 0.54 mg/kg

Background: The registrant is applying for registration of spot on products with claims of killing/controlling adult fleas, flea eggs/larvae and lice on dogs

#### Summary of MRIDs:

MRID 43679609 - Supports claims: kills/controls adult fleas on dogs for 1 month (study conducted on imidacloprid)

MRID 43679610 - Supports claims: kills/controls adult flea on dogs for 1 month (study conducted on imidacloprid)

MRID 47190401 - Supports lice claims for one month (study conducted on combination of imidacloprid + pyriproxyfen)

#### The following MRIDs were found unacceptable:

MRID 44256902 - Study on flea eggs from dogs. Not sufficient sample size used in the study. Study design no longer acceptable. Study does not support any claims.

MRID 44256903 - Not a valid MRID number.

MRID 45425101 - Study on adult fleas on dogs. Study design is not acceptable. Study does not support any claims.

MRID 45425102 - Study on adult fleas on cat fur. Study design is not acceptable. Study does not support any claims.

#### Recommendations:

The cited MRIDs 43679609, 43679610 & 47190401 cumulatively support general kills/controls claims against adult fleas and lice for 1 month. This does not include Bayer's "kills fleas on dogs for 12 hour claim," flea egg/larvae claims, waterproof nor shampooing claims.

1



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

April 17, 2014

#### MEMORANDUM: CAS STUDIES CITED FOR 2596-RIE

Subject:

Name of Pesticide Product: Hartz Reference #147

EPA Reg. No. /File Symbol: 2596-RIE

DP Barcode:

DP 419029

Decision No.:

486441

Action Code:

R315

Submission:

#945492

E-Sub.

PC Codes:

129099 (Imidacloprid: 9.1%)

129032 (Pyriproxyfen: 0.46%)

cologist Byo 1. B

April - 17-2014

My Chil

From:

Byron T. Backus, Ph.D., Toxicologist

Technical Review Branch

Registration Division (7505P)

To:

Autumn Metzger/Venus Eagle RM 01

Insecticide-Rodenticide Branch Registration Division (7505P)

Registrant:

HARTZ REFERENCE #147

#### FORMULATION FROM LABEL:

Active Ingredient(s):		by wt.
129099 Imidacloprid	*	9.10%
129032 Pyriproxyfen		0.46%
Other Ingredients:		90.44%
	TOTAL	100.00%

**ACTION REQUESTED:** "This new product is citing 2 C.A. studies. Please review and make sure they will support this new product."

**BACKGROUND:** The material received by TRB includes a cover letter (dated December 23, 2013) from the registrant, a data matrix, a CSF, and a proposed label with the signal word CAUTION. According to the data matrix, the registrant is citing companion animal safety studies in MRIDs 45097101 and 45097102 to satisfy the 870.7200 data requirements.

# COMMENTS AND RECOMMENDATIONS:

- 1. The companion animal safety studies in MRID 45097101 (puppy study) and 45097102 (adult dog study) were originally submitted to support the following Bayer Healthcare registrations: 11556-125 (dogs and puppies 7 weeks and older weighing 11-20 lbs; dosage rate: 0.034 fl. oz. or 1.0 mL); 11556-127 (dogs and puppies 7 weeks and older weighing 21-55 lbs; dosage rate: 0.085 fl. oz. or 2.5 mL); 11556-130 (dogs and puppies 7 weeks and older weighing over 55 lbs; dosage rate: 0.135 fl. oz. or 4.0 mL); and 11556-128 (dogs and puppies 7 weeks and older weighing 3-10 lbs; dosage rate: 0.014 fl. oz. or 0.4 mL). Each of these Bayer Healthcare registrations has a label declaration of 9.10% imidacloprid and 0.46% pyriproxyfen. Bayer Healthcare was the submitter, not the Hartz Mountain Corporation (which is indicated in the data matrix).
- 2. The proposed product 2596-RIE also has a label declaration of 9.10% imidacloprid and 0.46% pyriproxyfen.
- According to the proposed label for 2596-RIE, the following are the proposed dosages and corresponding dog/puppy weight ranges for this product: 0.014 fl. oz. (0.4 mL): 3-10 lbs; 0.034 fl. oz. (1.0 mL): 11-20 lbs; 0.084 fl. oz. (2.5 mL): 21-55 lbs; 0.135 fl. oz. (4.0 mL): >55 lbs.
  - These dosage rates and corresponding dog/puppy weight ranges are consistent with those of the Bayer Healthcare products. However, after examining the data in MRID 45097101, it is concluded that 2596-RIE has a slightly greater (~4.0%) specific gravity than the formulation that was tested in MRID 45097101.
- 4. Because of the higher specific gravity, dogs would be exposed to ~4.0% more imidacloprid than from the equivalent Bayer product (the pyriproxyfen is not an issue, as the studies in MRIDs 45097101 and 45097102 were on a formulation or formulations containing 0.9% pyriproxyfen). However, the TRB review (TXR 5001580) dated September 8, 2000 states: "Both the puppy study (MRID 45097101) and the adult dog study (MRID 45097102) have been classified as acceptable. For both studies, the lack of any indications of a consistent toxicological response following exposures (4 in each study) to 5X levels of the label-specified application rates indicates that an adequate safety margin exists for this formulation and its proposed use on puppies 7 weeks old and older as well as adult dogs." Since the exposure increase to imidacloprid is less than 5%, and there were no indications of toxicity in the cited companion animal safety studies, TRB concludes that all CAS study requirements (870.7200) for the registration of 2596-RIE have been satisfied by citations to MRIDs 45097101 and 45097102.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

April 16, 2014

# MEMORANDUM: HARTZ REFERENCE #147 ACUTE TOXICITY STUDY DERS

Subject:

Name of Pesticide Product: Hartz Reference #147

EPA Reg. No. /File Symbol: 2596-RIE

DP Barcode:

DP 419023

Decision No.:

486441

Action Code:

R315

Submission:

#945492

E-Sub.

PC Code:

129099 (Imidacloprid: 9.1%)

129032 (Pyriproxyfen: 0.46%) Byrat. Bolo April-16-2014 MHadin

From:

Byron T. Backus, Ph.D., Toxicologist

Technical Review Branch

Registration Division (7505P)

To:

Autumn Metzger/Venus Eagle RM 01

Insecticide-Rodenticide Branch Registration Division (7505P)

Registrant:

HARTZ REFERENCE #147

FORMULATION FROM LABEL:

Active Ingredient(s): 129099 Imidacloprid 129032 Pyriproxyfen Other Ingredients:

by wt. 9.10%

0.46%

TOTAL

90.44% 100.00%

ACTION REQUESTED: "Please review package, data and CSF for the submitted new product. The MRIDs were also submitted to support EPA File symbol 2596-RIG.

**BACKGROUND:** The material received by TRB includes a cover letter (dated December 23, 2013) from the registrant, a data matrix, a CSF, and a proposed label with the signal word CAUTION.

#### COMMENTS AND RECOMMENDATIONS:

- TRB has reviewed the five acute toxicity studies in MRIDs 49287804 through 49287808, and a request for a waiver of the inhalation study data requirement (MRID 49287809).
- 2. The five studies are all classified as acceptable and the inhalation study can be waived with assignment of the formulation to toxicity category IV by that exposure route.
- 3. The acute toxicity data requirements for the registration of 2596-RIE have been satisfied.
- Based on the results from the acute toxicity studies, the following is the acute toxicity profile of EPA File Symbol 2596-RIE:

Oral LD50	Toxicity Category III	MRID 49287804	Acceptable
Dermal LD50	Toxicity Category IV	MRID 49287805	Acceptable
Inhalation LC50	Toxicity Category IV	-	Waived
Eye Irritation	Toxicity Category III	MRID 49287806	Acceptable
<b>Dermal Irritation</b>	Toxicity Category IV	MRID 49287807	Acceptable
<b>Dermal Sensitization</b>	Non-Sensitizer	MRID 49287808	Acceptable

Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 2596-RIE as obtained from the Precautionary Labeling System:

PRODUCT ID #:

002596-00182

PRODUCT NAME:

**HARTZ REFERENCE #147** 

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

# **Hazards to Humans and Domestic Animals:**

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing. [Wear protective eyewear.]\* Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

<sup>\*[</sup>Protective eyewear may be specified, if appropriate].

# First Aid:

#### If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

### If in eyes:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

The CSF (dated December 1, 2013) for 2596-RIE should also be reviewed and accepted by the TRB Chemistry Team. Reviewer: Byron T. Backus, Ph.D.

Date: April 16, 2014 Risk Manager (EPA): 01

The following is the Acute Toxicity Data Evaluation Record (DER) for the acute toxicity studies (MRIDs 49287804 through 49287808) submitted in support of EPA File Symbol 2596-RIE.

1. DP BARCODE: 419023

2. PC CODES: 129099 (Imidacloprid), 129032 (Pyriproxyfen)

3. CURRENT DATE: April 16, 2014

**4. TEST MATERIAL:** Dermal Treatment TS# 13825; containing 9.1% Imidacloprid and 0.46% Nylar (Pyriproxyfen) as active ingredients; described as a light amber liquid with a density of 1.143 g/mL.

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat / Product Safety Labs, Dayton NJ / Lab Study No. 37575 / November 19, 2013 / OCSPP 870.1100; OECD 425	49287804	Dosages: 1040 mg/kg (2 rats); 1650 mg/kg (2 rats); 2600 mg/kg (1 rats). Rat dosed at 2600 mg/kg and one at 1650 mg/kg died; two rats dosed at 1040 mg/kg and one dosed at 1650 mg/kg survived. LD50 = 1650 mg/kg with ~95% C.L. of 895.3 to >20000 mg/kg. At 1040 mg/kg both rats were hypoactive with irregular respiration & reduced fecal volume, but recovered by day 3. At 1650 mg/kg one was dead on day 2; prior to death signs were prone posture, irregular respiration & clear ocular discharge; other rat dosed at 1650 mg/kg had hunched posture, irregular respiration, hypoactivity and reduced fecal volume with recovery by day 2. At 2600 mg/kg rat showed prone posture and irregular respiration 1-3 hour after dosage with death at 4 hours. Gross necropsy: no abnormalities in survivors; at 1650 mg/kg dead rat had slightly red lungs and extremely	III	A
		distended stomach & intestines. At 2600 mg/kg stomach slightly distended filled with clear liquid and intestines red in color.	8	

Acute dermal toxicity / rat / Product Safety Labs, Dayton NJ / Lab Study No. 37658 / December 2, 2013 / OCSPP 870.1200; OECD 402	49287805	5000 mg/kg applied to 5M & 5F rats, with 24-hr dermal exposure. No mortality or signs of systemic toxicity. One male & one female had dermal irritation which cleared by day 2. All gained weight days 0-7 and 7-14. There were no gross abnormalities at necropsy.	IV	A
Acute inhalation toxicity / rat /	49287809 (waiver request)	Product is a liquid with low volatility; with at most 4 mLs as a single dose applied to skin of companion animals.	IV	W
Primary eye irritation / rabbit / Product Safety Labs, Dayton NJ / Lab Study No. 37659 / December 3, 2013 / OCSPP 870.2400; OECD 405	49287806	0.1 mL instilled in right eye of each of 3 rabbits. At 24 hrs all eyes were positive for corneal opacity and conjunctival irritation. Two eyes were positive for conjunctival irritation at 48 hours. All eyes had completely cleared (all scores zero) at 72 hours. MMTS = 12.3 (24 hrs).	III	A
Primary dermal irritation / rabbit / Product Safety Labs, Dayton NJ / Lab Study No. 37660 / December 2, 2013 / OCSPP 870.2500; OECD 404	49287807	Each of 3 rabbits received 4-hr dermal semi-occlusive exposure to 0.5 mL test material. All scores zero at ½-1, 24, 48 & 72 hrs. PDII = 0.0	IV	A
Dermal sensitization / guinea pig / Product Safety Labs, Dayton NJ / Lab Study No. 37661 / December 12, 2013 / OCSPP 870.2600; OECD 406	49287808	Buehler Method: 20M (from p. 8 of report; from p. 16 it was 20F) guinea pigs received 3 once-a-week 6-hr induction treatments to 0.4 mL undiluted test material on left side of each animal. 27 days after first induction dose 0.4 mL undiluted (HNIC) test material was applied to a site on right side; at this time an additional 10 (male or female) naïve guinea pigs were also exposed to the same dose. All 30 of the exposed guinea pigs scored zero at 24 and 48	Not a sen- siti- zer	A
n d = not determined: Com		hours. Positive control substance gave appropriate response.		

n.d. = not determined; Core Grade Key: A = Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap

# Metzger, Autumn

From:

DJones@hartz.com

Sent:

Monday, April 21, 2014 9:41 AM

To:

Metzger, Autumn

Subject:

Re: EPA File Symbols: 2596-RIE and 2596-RIN application package issues

Attachments:

2014 Apr 21 Formul Exempt Hartz Ref 147 signed.pdf; Data Matrix Hartz Ref 147 2014 Apr 21 public signed.pdf; Data Matrix Hartz Ref 147 2014 Apr 21 signed.pdf

Good morning,

Attached please find the Formulator's exemption statement and Data Matrix full and public for EPA File Symbol 2596-RIE modified as indicated below. This should reconcile these issues for both. Please let me know if you did not get the 2596-RIN e-mail earlier today or if there are any other items I can help resolve.

Thank you,

Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From:

"Metzger, Autumn" <Metzger.Autumn@epa.gov>

To: "djones@hartz.com" <djones@hartz.com>,

Date: 04/10/2014 11:55 AM

Subject:

EPA File Symbols: 2596-RIE and 2596-RIN application package issues

Mr. Jones,

As stated on my voicemail the above mentioned packages for the corresponding products have some issues that need to be revised:

- The formulator's exemption form does not match the CSF. Please revise the imidacloprid source appropriately.
- The data matrix form was not filled out accurately. Many of the data submitted is owned by Bayer, not Hartz. Revise accordingly. In addition, add for each efficacy study cited the pest, site or claim that each will represent (i.e. adult fleas, flea eggs, water immersion claim, etc.)

Autumn Metzger Registration Division Office of Pesticide Programs U.S. EPA 703-305-5314



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

January 23, 2014

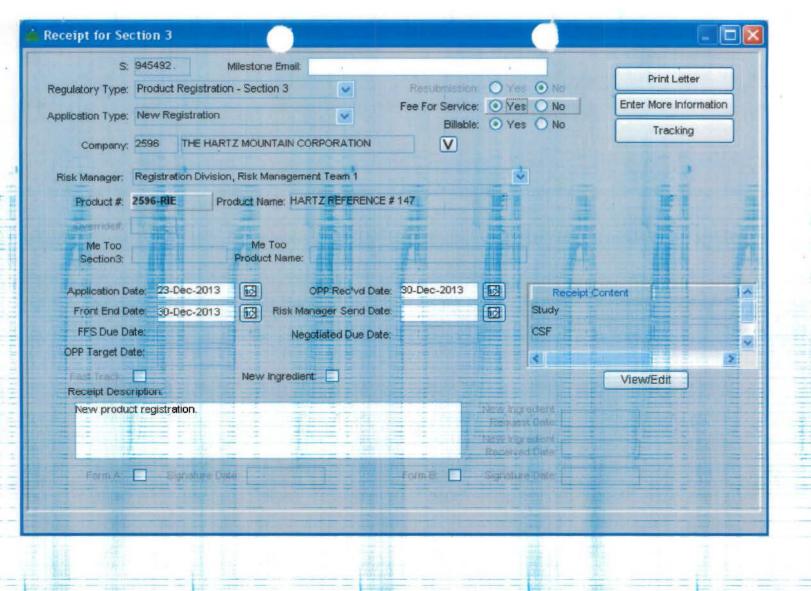
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

THE HARTZ MOUNTAIN CORPORATION 400 PLAZA DRIVE SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 30-DEC-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



# PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12 - 30	- /3				
Experts In-Processing Signature:	B.B.		Date 1-6-14	Fee Paid:	Yes 🗸
Division management contacted on issues	No	Yes	Date		_

	Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including type	kage	X			
1	Confidential Statement of Formula all boxes completed, form s dated (EPA Form 8570-4)	signed, a	nd	X		
2	a) All inerts, including fragrances, approved for the proposed yes no					
	uses (see Footnote A)					
Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)						
Certificate and data matrix consistent						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)					
	If applicable, is there a letter of Authorization for exclusive use or	nly.				
Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)						
	Data Matrix (EPA Form 8570-35) both internal and external cop completed and signed (N/A if 100% repack)	ies (PR	98-5)	X		
_		yes	no			
5	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged an available)	d guida	nce is	X		
6		d guida	nce is	X		

9	If applicable for conventional applications, reduced risk rationale	
	Required Data and/or data waivers. See Footnote C.	
	a) List study (or studies) not included with application	
10		

# Comments:

- + Deficiences w/ submiffed studies:
  - · 402878 09: The study aid not have a statement of confidentiality | nonconfidentiality
- \* mays approved for non-food use
- \* Emailed submiffer on 01/14/2014
- + received corrections on oi/14/2014
- \* Submiffed studies FASSED PRN 11-3 raview
- \* lacket FASSED

MRID: 492878

# Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency even if a product is currently registered by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at <a href="inertsbranch@epa.gov">inertsbranch@epa.gov</a> and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the <a href="Chief of Microbial Pesticides Branch">Chief of Microbial Pesticides Branch</a>.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

# Unapproved Inerts Identified on CSFs

# All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

# PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

# Correa, Leah

From:

DJones@hartz.com

Sent:

Wednesday, January 15, 2014 10:54 AM

To: Cc: Correa, Leah Ashe, Anthony

Subject:

Re: Submissions to EPA: Products Hartz Reference #147 (EPA Reg# 2596-RIE) and Hartz

Reference #148 (EPA Reg# 2596-RIG)

Attachments:

2014 Jan 14 Hartz Ref 147 No Data Conf pg vol 9 signed.pdf; 2014 Jan 14 Hartz Ref 148 No

Data Conf pg vol 9 signed.pdf

Good morning Leah,

Thank you for bringing these to my attention. I had prepared the inserts earlier. Scans of them are attached. If I need to modify them, please let me know.

Sincerely, Dave

David Jones

Manager Regulatory Affairs
The Hartz Mountain Corporation

400 Plaza Drive

Secaucus, NJ 07094 TEL: 201-271-4800 x 7414

FAX: 201-271-0357

From: To: "Correa, Leah" < Correa, Leah@epa.gov>
"DJones@hartz.com" < DJones@hartz.com>,
"Ashe, Anthony" < Ashe, Anthony@epa.gov>

Cc: "Ashe, Anthony" < Ashe. Date: 01/14/2014 05:47 PM

Submissions to EPA: Products Hartz Reference #147 (EPA Reg# 2596-RIE) and Hartz Reference #148 (EPA Reg# 2596-RIG)

Good Afternoon, Mr. Jones:

This e-mail is to address an issue found in the submitted studies associated with your applications for registration of products Hartz Reference #147 (EPA Reg# 2596-RIE) and Hartz Reference #148 (EPA Reg# 2596-RIG):

The same issue applies for both of the following studies:

Hartz Reference #147 (EPA Reg# 2596-RIE)

Volume 9: Supplemental Information: Acute Inhalation Toxicity Waiver Request: Chemistry Data Waivers

Hartz Reference #148 (EPA Reg# 2596-RIG)

Volume 9: Supplemental Information: Acute Inhalation Toxicity Waiver Request: Chemistry Data Waivers

For the two studies listed above, you must include an acceptable statement of data confidentiality or non-confidentiality on page 2 (or make a page-2a) of each study.

Please verify and send the corrections either by e-mail or through our secure fax line as soon as possible. If you have any questions, please do not hesitate to contact me.

Best Regards,

Leah

Leah M. Correa - EPA Contractor

2777 S. Crystal Drive, S-4811, Arlington, VA 22202 Phone: (703) 305-0074; Fax: (703) 305-5060 correa.leah@epa.gov



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

January 3, 2014

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP Decision Number: D-486441

EPA File Symbol or Registration Number: 2596-RIE

Product Name: HARTZ REFERENCE # 147

EPA Receipt Date: 30-Dec-2013 EPA Company Number: 2596

Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

# Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES; INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:; PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY); ANIMAL SAFETY STUDIES; CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

# Fee for Service

{945492=~

This package includes the following	for Division
<ul> <li>New Registration</li> <li>Amendment</li> <li>✓ Studies?</li> <li>□ Fee Waiver?</li> <li>□ volpay</li> <li>% Reduction:</li> </ul>	OAD OBPPD ORD Risk Mgr. 1
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	945492 2596-RIE 12/30/2013
This item is NOT subject to  Action Code:  Requested: \$\( \alpha \) 3/5  Granted: \$\( \alpha \) 3/5  Amount Due: \$\( \delta \) 4/40	Parent/Child Decisions:
Inert Cleared for Intended Use  Reviewer:  Remarks:  - Shows PC/acuti  - Sites same CAS	Uncleared Inert in Product  Date: 1/2/14  Tox w - R16  efficiency structus as - R1N

AIN CORPORATION

SECAUCUS, NJ 07094

LIC ENVIDONMENTAL DOCTEO

ATE: 19-DE	EC-13 VEN	IDOR NAME: US ENVIRONMENTAL PROTEC	VENDOR NO: 1992	
INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
AS FEE	02-DEC-13	1000086085 P- (PRIA) code R315	0.00	8,400.0
			State of the state of the state of	
		왜 시크림을 하는 건 보는 옷이 어느리를 들었다.		
	The Name of Street, St			
	Maria Maria			
	The State of the S			
1118				
		71	al- V/al 0.00	0.400.0

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT.

Thank You!

8,400.00

THE HARTZ MOUNTAIN CORPORATION 400 PLAZA DRIVE SECAUCUS NJ, 07094

Bank of America

64-1278

No.

326830

CHECK DATE 19-DEC-13 CHECK NUMBER 326830

CHECK AMOUNT \*\*\*\*\*\*8,400.00

PAY

TO THE ORDER

OF

US ENVIRONMENTAL PROTECTION AGENCY PESTICIDE REGISTRATION SERVICE FEE

PO BOX 979031 ST LOUIS, MO 63197-9000

\*Commercial/financial information may be entitled to confidential treatment\*



# LIST OF DATA SUBMITTERS SENT OFFER-TO-PAY LETTERS

Application for Hartz Reference #147

Spot On Data for Products with:

Imidacloprid (Case #7605) 0.91% Pyriproxyfen (Case #7424) 0.46%

Selective Citation Method - Only one data owner

EPA Company No. 11556
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
ATTN: DR. BRUCE MARTIN
PO BOX 390
SHAWNEE MISSION, KS 66201

Please read instructions	on reverse before complet	ting form.			Form Appr	ov	OMB No. 20	70-0060	Print Form
<b>\$EPA</b>	Environmental	Protections		ncy		×	Registra Amendr Other		OPP Identifier Number
		Application	n for F	esticio	le - Sec	tion	ı		
1. Company/Product Nu 2596-	mber			2. EPA F V. Eagl	Product Man	ager			roposed Classification
4. Company/Product (Na HARTZ Reference #1				PM#				٦Ľ	None Restricted
The Hartz Mountain 400 Plaza Drive Secaucus, NJ 07094-		de)		(b)(i), m to: EPA P Produ	teg. No	is sim			FIFRA Section 3(c)(3) omposition and labeling
			Sec	tion - I	<u>'                                     </u>				
Amendment - Ex	response to Agency letter	dated	<del></del>	-    -    X	Final printe Agency let "Me Too". Other - Exp	ter dat Applica	ation.	e to	
			Sect	tion - I	II				
1. Material This Produc			T						
Child-Resistant Packagi Yes*  X No  * Certification mus	× Yes	No. per	X	Yes No	No. per		2. Type of	Metal Plastic Glass Paper	r Specify)
be submitted	2 to 9 g	1 to 10	Tacka	je wyt	I	,,		J Other (	Specify/
3. Location of Net Cont    X   Label	ents Information  Container	4. Size(s) Re 1 to 10 tube		ner		5. Lo	On Labe	ı	ons mpanying product
6. Manner in Which Lab	pel is Affixed to Product	Lithog Paper Stence	graph glued iled		X Othe	Pri	nted		
			THE RESERVE OF THE PERSON NAMED IN	ion - l'	V				
1. Contact Point /Com	plete items directly below	for identification	on of indiv	idual to b	e contected	, if nec	cessery, to pr	ocess thi	s application.)
Name David Jones			Title Mgr. Re	gulatory	Affairs			Telephoi 201.27	ne No. (Include Area Code) 1.4830
S	statements I have made or at any knowingly false or r sable law.		d all attack						8. Date Application Received (Stamped)
2. Signature La	Ad		3. Title Manage	r Regula	tory Affairs	;			
4. Typed Name			5. Date						
David Jones			Dec. 23, 2013						





# THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800 REGULATORY AFFAIRS

December 23, 2013

FedEx Delivery

Document Processing Desk (Distribution Code-REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: New Pesticide Product Application, Hartz Reference #147

Dear Sir/Madam,

Enclosed please find a pesticide registration application package for Hartz Reference #147. Included after the Transmittal Document are the usual and customary support materials. Hartz would like to point out that the toxicology reports are identical for the Hartz Reference #s 147 and 148 to help the Agency avoid duplicate reviews.

Enclosed is a check payable to the US Environmental Protection Agency in the amount of \$8400. This is to cover the PRIA Code R315.

Direct contact by phone or e-mail is welcomed if I can assist in the processing of information presented in this package.

Sincerely,

David Jones

Manager Regulatory Affairs The Hartz Mountain Corporation (201) 271-4800, ext. 7414

djones@hartz.com

Encl.

# TRANSMITTAL DOCUMENT

# Submitter:

The Hartz Mountain Corporation 400 Plaza Drive

Secaucus, NJ 07094-3688

Company Contact:

Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

# Regulatory Action in Support of Which This Package is Submitted:

EPA Reg. No. 2596-\_\_\_; HARTZ Reference #147; PRIA Code R315; \$8400

New product application. Acute toxicology data and chemistry data are included in package. Data matrix: Selective Citations.

#### **Submission Date:**

12/23/2013

# List of Submitted Documents:

Cover letter

Application Form

Confidential Statement of Formula (2 copies)

Formulator's Exemption Statement

Certification with Respect to Data with list

Data Matrix

Data Matrix, confidential public copy

# TRANSMITTAL DOCUMENT

for acute to x and product chem!

Proposed Label Text (Five copies)

PRIA Fee, Check No. for \$8400.00

49287801 Volume 1 - Product Chemistry with Self-Certification

49287802 Volume 2 - Product Chemistry, Confidential Sections

49287803 Volume 3 – Product Chemistry Enforcement Analytical Method

49287804 Volume 4 - Acute Oral Toxicity

49287805 Volume 5 – Acute Dermal Toxicity

49287806 Volume 6 - Primary Eye Irritation

49287807 Volume 7 - Primary Skin Irritation

49287808 Volume 8 - Dermal Sensitization Study

49287809 Volume 9 - Data Waiver Requests

# \*Product ingredient source information may be entitled to confidential treatment\*

Form approved. OMB No. 2070-0060, 2070-0067, 2070-0107, 2070-0122, 2070-0164.

	7/4

United States

#### Environmental Protection Agency Washington, DC 20460

# Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address The Hartz Mountain Corporation	EPA File Symbol/Registration Number 2596-RIE
400 Plaza Drive Secaucus, NJ 07094	Product Name Hartz Reference #147
	Date of Confidential Statement of Formula (EPA Form 8570-4) 12/01/2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid Pyriproxyfen

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement.

  That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

	Source	
Active Ingredient Imidacloprid	Product Name	Registration Number
Pyriproxyfen		
rynproxyten		
Signature / A	Name and Title	Date
Dalf	David Jones/Mgr. Reg. Affairs	04/22/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA Copy 2 - Applicant copy



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

WASHINGTON	, D.C. 20460	**		
Paperwork Reduction Act Notice: The public reporting burden for this collection of information and 0.25 hours per response for reregistration and special review activities, including time for recomments regarding burden estimate or any other aspect of this collection of information, inclustrategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avento this address.	eading the instructions uding suggestions for a	s and completing the necessary forms. Send reducing the burden to: Director, Collection		
Certification with Respect to C	Citation of Data			
Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corp., 400 Plaza Dr., Secaucus, NJ 07094; (201) 271-4800	EPA Registration Number/File Symbol 2596-			
Active Ingredient(s) and/or representative test compound(s) Imidacloprid and Pyriproxyfen		Date Dec. 23, 2013		
General Use Pattem(s) (list all those claimed for this product using 40 CFR Part 158 Residential Indoor Use		Product Name Hartz Reference #147		
NOTE: If your product is a 100% repackaging of another purchased EPA-registere submit this form. You must submit the Formulator's Exemption Statement (EPA Form		r all the same uses on your label, you do not need to		
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies se	nt offers of compensation (the Data Matrix form should		
SECTION I: METHOD OF DATA SUPP	ORT (Check one m	ethod only)		
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	g the selective method of support (or cite-all option selective method), and have included with this form a d list of data requirements (the Data Matrix form must be		
SECTION II: GENERAL	OFFER TO PAY			
[Required if using the cite-all method or when using the cite-all option under the selection of the selectio				
SECTION III: CERT	IFICATION			
I certify that this application for registration, this form for reregistration, or the application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application sour uses.  I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	addition, if the cite- t (1) concern the pro- is a type of data that ght the initial registra- or reregistration, the	all option or cite-all option under the selective method is operties or effects of this product or an identical or twould be required to be submitted under the data attion of a product of identical or similar composition and at I am the original data submitter or that I have obtained		
I certify that for each study cited in support of this registration or reregistration submitter; (b) I have obtained the permission of the original data submitter to use the compensation have expired for the study; (d) the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(amount and terms of compensation, if any, to be paid for the use of the study.	study in support of the large o	his application; (c) all periods of eligibility for iting the company that submitted the study and have nd (ii) to commence negotiations to determine the		
I certify that in all instances where an offer of compensation is required, cop- accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will in evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	be submitted to the	Agency upon request. Should I fail to produce such		
I certify that the statements I have made on this form and all attachm knowingly false or misleading statement may be punishable by fine or impriso				
Signature	Date Dec. 23, 2013	Typed or Printed Name and Title David Jones/Mgr. Regulatory Affairs		

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date 5/15/2014  Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		EPA Reg No./File Symbol 2596-RIE		Page 1 of 3	
		Product Hartz Reference #147			
Ingredient Imidacloprid 9.1%/ Pyr	iproxyfen 0.46%				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identification and Composition	Submitted	The Hartz Mountain Corporation	own	
830.1600	Description of Materials Used to Produce the Product	Submitted	The Hartz Mountain Corporation	own	
830.1620	Description of the Production Process	Submitted	The Hartz Mountain Corporation	own	
830.1650	Description of the Formulation Process	Submitted	The Hartz Mountain Corporation	own	
830.1670	Discussion of Formation of Impurities	Submitted	The Hartz Mountain Corporation	own	
830.7100	Viscosity	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.1750	Certified Limits	Submitted	The Hartz Mountain Corporation	own	
830.1800	Enforcement Analytical Method	Submitted	The Hartz Mountain Corporation	own	
830.6302	Color	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6303	Physical State	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6304	Odor	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver Request	The Hartz Mountain Corporation	own	
830.6315	Flammability	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6316	Explodability	Waiver Request	The Hartz Mountain Corporation	own	
830.6317	Storage Stability	To be submitted	The Hartz Mountain Corporation	own	In process
Signature David Jones		Name and Title David Jones/Manager Regulatory Affairs		Date 05/15/2014	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	מ	ATA MATRIX			
Date 5/15/2014  Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		EPA Reg No./File Symbol 2596-RIE		Page 2 of 3	
		Product Hartz Reference #147			
Ingredient Imidacloprid 9.1%/ Pyr	iproxyfen 0.46%	*			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6320	Corrosion Characteristics	To be submitted	The Hartz Mountain Corporation	own	In process
830.6321	Dielectric Breakdown Voltage	Waiver request	The Hartz Mountain Corporation	own	
830.7000	pH	Waiver request	The Hartz Mountain Corporation	own	
830.7300	Density/Relative Density/Bulk Density	Submitted	The Hartz Mountain Corporation	own	Self-Certification
870.1100	Acute Oral Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1200	Acute Dermal Toxicity	Submitted	The Hartz Mountain Corporation	own	
370.1300	Acute Inhalation Toxicity	Waiver request	The Hartz Mountain Corporation	own	
370.2400	Acute Eye Irritation	Submitted	The Hartz Mountain Corporation	own	
370.2500	Acute Dermal Irritation	Submitted	The Hartz Mountain Corporation	own	
370.2600	Skin Sensitization	Submitted	The Hartz Mountain Corporation	own	
370.7200	Companion Animal Safety Study	45097101	Bayer Healthcare	PAY	-
370.7200	Companion Animal Safety Study	45097102	Bayer Healthcare	PAY	
10.3300	Treatments to Control Pests of Humans and Pets	47190401	Bayer Healthcare	PAY	
10.3300	Treatments to Control Pests of Humans and Pets	43679609	Bayer Healthcare	OLD	
Signature Daille		Name and Title David Jones/Manager Regulatory Affairs		Date 05/15/2014	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date 5/15/2014  Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		EPA Reg No./File Symbol 2596-RIE		Page 3 of 3	
		Product Hartz Reference #147			
Ingredient Imidacloprid 9.1%/ Pyr	iproxyfen 0.46%				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
95-9	Product Performance (Efficacy)	43679610	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	44256902	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	44256903	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	45425101	Bayer Healthcare	PAY	
95-9	Product Performance (Efficacy)	45425102	Bayer Healthcare	PAY	
95-9	Product Performance (Efficacy)	44256901	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	44256901	Bayer Healthcare	OLD	
310.3300	Product Performance (Efficacy)	47109101	Bayer Healthcare	PAY	
310.3300	Product Performance (Efficacy)	47298201	Bayer Healthcare	PAY	
310.3300	Product Performance (Efficacy)	48240118	Bayer Healthcare	PAY	
	*		711/0.14		
Signature Davilfore			Name and Title  David Jones/Manager Regulatory Affairs		Date 05/15/2014

EPA Form 8570-35 (9-97). Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

